EXHIBIT B

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EXHIBIT B

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November 29, 2018

VIA PRIORITY MAIL

Judge Ryan Glaze
OMHA Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114

RE: Prehearing Brief
ALJ Appeal No. 1-8071086400
Appellant/Beneficiary: M. Piekanski
Service: E0766
Dates of Services: 12/14/17, 1/14/18, 2/14/18
Hearing Date: To Be Determined
Our Ref. No.: 18-84

Dear Judge Glaze:

In anticipation of the scheduling of the above-captioned case, please find attached a prehearing brief to aid in your analysis. In the interest of efficiency and consistency, we previously requested aggregation of these claims with prior pending claims. The request was denied, but please find enclosed the decision with respect to the prior dates of service.

If you have any questions regarding the foregoing, please do not hesitate to contact me at (412) 561-6250. We appreciate your consideration.

Respectfully submitted,

Debra M. Parrish

Debra M. Parrish
Attorney for M. Piekanski

Enclosures:
Prehearing Brief
Attachment A: Prior ALJ Gulin Decision
Attachment B: Letter from DMAC Medical Directors

cc: Ms. Piekanski

PREHEARING BRIEF - JUDGE RYAN GLAZE
ALJ APPEAL NO. 1-8071086400
APPELLANT: M. PIEKANSKI
DOS: 12/14/17, 1/14/18, 2/14/18
HEARING DATE: TO BE DETERMINED
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A. Background

Ms. Mauareen Piekanski, a 63-year-old Medicare beneficiary, homemaker and clerk, was diagnosed with a glioblastoma in 2011. Her clinician prescribed chemotherapy, radiation, and the Optune system to treat her glioblastoma, in addition to having surgery. The supplier submitted claims for the Optune system to the relevant Durable Medical Equipment Contractor (DMAC) which denied the claims on the basis that the device is not covered by Medicare. The QIC argued that there is insufficient documentation to "quantify the effects" of the device, and the manufacturer's price was not submitted. LCD L34823 is generally mentioned. As described more fully below, the denial is inconsistent with Medicare coverage criteria and the record.

This issue has already been adjudicated through the Medicare appeals process. See attached prior ALJ decision. Administrative Law Judges are not bound by LCDs. 42 C.F.R. § 405.1062(a). Given the rarity of the disease and its limited treatment options, in addition to the substantial support for the effectiveness of the device as represented by clinical study outcomes, professional societies, the FDA, and other payers' policies, the LCD should not be deferred to for Ms. Piekanski's claims.

1. Glioblastoma Multiforme (GBM)

Glioblastoma is the most common form of primary brain cancer but is still very rare (~ 10,000 cases annually in the U.S.). The NIH designates GBM as a rare disease, with few treatment options. See e.g., https://rarediseases.info.nih.gov/diseases/2491/glioblastoma. GBM tumors are typically highly aggressive. The disease is labeled "recurrent" GBM when the tumor recurs or progresses after initial treatment. Recurrent GBM is an end-stage condition. It is uniformly fatal with 1-year survival of about 10%. When GBM recurs, only 20% of patients are eligible for re-operation. As a result, patients with recurrent GBM face severely limited treatment options. After being diagnosed with recurrent GBM, average overall survival is approximately 6 months from the time of recurrence without additional effective treatment.[1] Survival at initial presentation is approximately 10 months, even with aggressive chemotherapy.[2] Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy.

2. Optune (formerly NovoTTF-100A System)

Optune, previously known as the NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or Tumor Treating Fields to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patient's scalp and deliver the Tumor Treating Fields Therapy ("TTFT") to the

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[1] Rulseh et al. "Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields." World Journal of Surgical Oncology at 1 (2012).
[2] Id.

patient's glioblastoma. Basically, the fields slow the replication of the cancer cells or stop their growth all together. The fields may also destroy some of the cancer cells.

Optune is FDA-approved for recurrent and newly diagnosed glioblastoma multiforme (GBM) brain tumors. On January 1, 2014, CMS classified the Optune device as DME requiring frequent and substantial servicing, which is billed under HCPCS code E0766 as a monthly rental through the duration of medical necessity. Optune has been shown to extend the lives of patients suffering from glioblastoma tumors.

B. Literature/Professional Societies

Optune is the subject of numerous peer-reviewed published studies that demonstrate the safety and efficacy of the Optune system and TTFT generally. The studies are reported in some of the most prestigious journals in our country, including JAMA (the Journal of the American Medical Association). See submitted studies. Optune is included in the National Comprehensive Cancer Network (NCCN) guidelines for recurrent glioblastoma and for newly diagnosed GBM in combination with temozolomide. See submitted guidelines. The studies concluded the following:

- The final analysis of the randomized phase 3 trial (695 patients) found that the addition of Optune to standard chemotherapy treatment "resulted in statistically significant improvement in progression-free survival and overall survival" over patients that were treated with chemotherapy alone. Stupp et al. at 2315 (JAMA 2017). See also, intcrim analysis of 315 patients from this study (adding Optune to maintenance chemotherapy "significantly prolonged progression-free and overall survival"). Stupp et al. at 2542 (JAMA 2015).

- These important results come after a ten-year period of more than 23 randomized trials of new treatment modalities or products for glioblastoma that all "failed to demonstrate improved survival." JAMA 2017 at 2314-2315.

- Remarkably, adding Optune to traditional chemotherapy treatment "resulted in statistically significant longer deterioration-free survival in global health status, physical and emotional functioning, pain, and weakness of legs." Taphoorn et al. at E7 (JAMA Oncology 2018).

- As far back as 2012, researchers reported that in a study of 237 patients that received either Optune treatment or chemotherapy, the treatment was at least as effective as chemotherapy alone in terms of median survival, without the toxicity risks. Stupp et al. at 8-9 (European J of Cancer 2012).

In particular for newly diagnosed glioblastoma, the NCCN guidelines (considered the gold standard for oncology management) give a level one recommendation for TTFT, i.e., a

consensus exists among the experts based on the highest levels of evidence, that the treatment is recommended. Thus, a consensus exists that the published peer-reviewed literature demonstrates the effectiveness of the device for newly diagnosed glioblastomas. To the extent the QIC denied the claim based on the lack of quantification of effectiveness of the device generally, the peer-reviewed literature shows the opposite. Indeed, the Data Safety Monitoring Board for the clinical trial for newly diagnosed glioblastoma (and patients that suffered recurrences during the trial) found the data so compelling, they recommended early termination and allowing patients who were not receiving the treatment to be able to cross over and receive the treatment, deeming it unethical to withhold it. The FDA agreed.

C. Widespread Adoption

Based on the strength of the peer-reviewed literature and the lack of medical alternatives, the Optune system has been certified at more than 800 cancer treatment centers and has been prescribed by over 1200 physicians in 50 states, the District of Columbia, and Puerto Rico, for over 7200 patients. Virtually every major payer in the United States covers the Optune system for individuals diagnosed with a glioblastoma. These payers include, among others, Highmark, Aetna, Anthem, Humana, Kaiser, UnitedHealthcare, Cigna, Harvard Pilgrim, Geisinger, HealthPartners, and several Blue Cross plans.

Indeed, support for the effectiveness and widespread adoption of the TTFT device is illustrated in CMS' assignment of a HCPCS code to the technology. When an existing HCPCS code does not adequately describe a device, a supplier applies to the HPCPS workgroup for a new HCPCS code. The code communicates relevant coverage decisions and criteria, fee schedule amounts, and billing information. In view of the criteria required to get a new HCPCS code, it is difficult for a DME device to obtain a HCPCS code. A review of the 2016-2017 DMEPOS HCPCS application summary documents reflects that only five new HCPCS codes were established although there were 63 new-code requests.[3]

For the HCPCS workgroup to award a HCPCS code for a device, CMS must have information that shows the technology (a) is deemed safe and effective by the FDA, (b) clinical studies demonstrate its use results in a significantly improved medical outcome or a significantly superior clinical outcome, (c) it is significantly functionally or therapeutically different from already-coded DME, and (d) has achieved sufficient adoption by the relevant medical community to justify the "administrative burden" of adding a new HCPCS code. See HCPCS Decision Tree included on the CD submitted with the request for hearing. Thus, CMS considers coverage criteria when awarding a HCPCS code.[4]

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[3] Revision requests were not included in the total number of code applications. June 7, 2017 and June 8, 2017 DMEPOS HCPCS Application Summaries available at: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Application-Summaries.html.

[4] See www.ncbi.nlm.gov/PMC/articles/PMC3865619 for an article "HCPCS Coding: An Integral Part of Your Reimbursement Strategy" by Marcia Nusgart.

D. The LCD

The LCD on its face does not reflect the current peer-reviewed literature, consensus of experts, and widespread adoption. The LCD currently is the subject of a reconsideration request based on the foregoing deficiencies. See attached letter. In either event, the DMAC medical directors have indicated that they do not believe that newly diagnosed GBM is addressed by the LCD, i.e., it is inapplicable to Ms. Piekanski's case for the dates of service at issue. Id. Accordingly, in view of the asserted inapplicability, and its obvious failure to meet the requirements of the Program Integrity Manual, the LCD should not be used to preclude Medicare coverage of a device that meets Medicare's coverage criteria and which is reasonable and medically necessary for the Medicare beneficiary.

E. Reimbursement Amount/Quantification of Effectiveness

To the extent the claim was denied on the basis that the quantification of the effectiveness for this beneficiary was not shown, Appellant notes such quantification is not required for Medicare coverage. To the extent the ALJ gives any consideration to such a basis of denial, Ms. Piekanski notes that every month of survival after 10 months since her diagnosis should adequately quantify the effectiveness of the device for her.

Pending resolution of whether the claims will be covered by Medicare, Novocure, the supplier, has not demanded payment from Ms. Piekanski. If Medicare coverage is found, payment for DME is made under a regulation, 42 C.F.R. §414.210(a), which states that:

> *. . . Medicare pays for [DME] . . .on the basis of 80 percent of the lesser of:*
>
> *(1) the actual charge for the item; [or]*
> *(2) the fee schedule amount for the item, as determined in accordance with §§414.220 through 414.232.*

Because no fee schedule exists, per the above regulation, reimbursement is due at 80% of the amount billed. See also Medicare Appeal Council Decision for ALJ 1-178898474. Contrary to the QIC's assertion, the manufacturer's price was included in the claim submitted.

F. Conclusion

This is the technology that clinicians treating central nervous system tumors have embraced. No basis exists to deny Medicare coverage of a device that is shown in the peer-reviewed literature to be a safe and effective treatment for glioblastoma, a life-threatening condition. The Optune system was approved as safe and effective by the FDA. The peer-reviewed literature further supports its efficacy and the improved clinical outcome of patients who use the device. It is incorporated in the NCCN guidelines (considered the gold standard for cancer care), and it enjoys widespread adoption by clinicians and all the major payers in the

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United States based on the foregoing. The DMAC medical directors have indicated the antiquated LCD does not apply to newly diagnosed glioblastomas and thus it should not be used to preclude coverage. The claim should be approved consistent with the prior determination.

Attachment: Letter from DMAC Medical Directors

ATTACHMENT A:

Prior Favorable ALJ Decision for Beneficiary

18-31

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Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2511 Jefferson Davis Highway, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
571-457-7270 (ALJ Gulin Team)
703-603-1812 (Fax)
866-231-3087 (Toll Free)

Date: November 7, 2018

Debra M. Parrish
788 Washington Road
Pittsburgh, PA 15228

NOTICE OF DECISION

Appellant: M. PIEKANSKI
OMHA Appeal Number: 1-7835229465

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

NOVOCURE INC.
195 Commerce Way
Portsmouth, NH 03801

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Enclosures:

OMHA-152, Decision
OMHA-001, Notice of Nondiscrimination
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington Field Office
Arlington, Virginia

Appellant:	**M. Piekanski**	ALJ Appeal No.:	**1-7835229465**
Beneficiary:	**M. Piekanski**	**Medicare Part B**	
HICN:	***0957A**	Before:	**Jeffrey S. Gulin** U.S. Administrative Law Judge

DECISION

After considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** decision is entered for the Appellant/Beneficiary.

PROCEDURAL HISTORY

Mrs. Piekanski ("Appellant/Beneficiary") seeks coverage for Elec Stim Cancer Treatment (E0766) provided on September 14, 2017, October 14, 2017, and November 14, 2017 ("the Dates of Service"). (Exh. 1, p. 3). Noridian, the Medicare Administrative Contractor ("MAC"), denied coverage initially and on redetermination. (Exh. 1, p. 8). Following the denial, the Appellant requested reconsideration from a Qualified Independent Contractor ("QIC"). On August 3, 2018, the QIC determined the local coverage determination states tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. In this instance, the submitted documentation indicates the Beneficiary has a diagnosis of glioblastoma multiform involving the left occipital lobe. However, the medical documentation does not support the need for the device. There is insufficient documentation to quantify the effects of the device. The currently published studies in the medical literature do not clearly document the effectiveness of this device. As such, payment cannot be allowed. Based on available documentation, the requirements of the LCD have not been met. (Exh. 1, p. 4). The QIC determined an Advance Beneficiary Notice ("ABN") was not issued and found the Provider liable. (Exh. 1, p. 5).

On August 27, 2018, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's request for review by an Administrative Law Judge ("ALJ"). (Exh. 3, p. 1). The amount in controversy meets the statutorily required amount for an ALJ hearing. Judge Jeffrey S. Gulin held a telephone conference hearing on October 17, 2018. Attorney Bridget Noonan provided testimony and/or argument for the Appellant and Mr. Dan McCoy, Case Manager, NovoCure, Inc., served as a witness and was sworn in and provided testimony and/or argument. There were no objections and all exhibits were admitted into the record. (Hearing CD).

ISSUES

1. Whether the Elec Stim Cancer Treatment (E0766) provided to the Beneficiary on the dates of service meet Medicare coverage criteria.

2. Whether the services provided are medically necessary under Section 1862(a)(1)(A) of the Social Security Act ("Act") and covered under Medicare.

3. If the services are found to be excluded from coverage under Section 1862(a)(1)(A), then another issue to be determined is whether payment may nevertheless be made to appellant under the limitation on liability provisions of Section 1879 of the Act.

FINDINGS OF FACT

1. The Beneficiary/Appellant is seeking Medicare coverage for Elec Stim Cancer Treatment (E0766) provided on the dates of service. (Exh. 1, p. 53).

2. The Beneficiary was diagnosed with glioblastoma multiform in 2011. (Exh. 2, pp. 1, 25). The attending physician sought coverage for Optune for the Beneficiary with newly diagnosed glioblastoma. (Exh. 2, p. 4). Optune was prescribed by the attending physician on April 28, 2017 for 6 months. (Exh. 2, p. 2). The treatment was again prescribed on October 10, 2017 for another 6 months. (Exh. 2, p. 1).

3. Assessment of need and the agreement with Novocure indicate the treatment would be administered in the home. (Exh. 2, pp. 6, 8).

4. An article included from NovoCure with the product dossier describes Food and Drug Administration ("FDA") approval for treatment of recurrent glioblastoma multiforme. (Exh. 2, p. 94). The FDA gave premarket approval ("PMA") for the device in 2011. (Exh. 2, p. 89).

5. A study published in the 2015 Journal of the American Medical Association ("JAMA") edition entitled "Maintenance Therapy with Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Gliobastoma – A Randomized Clinical Trial" found in the interim analysis of 315 patients with glioblastoma who completed standard chemo radiation therapy, adding TTFields to maintenance temozolomide chemotherapy significantly prolonged progress-free and overall survival. (Exh. 1, p. 92).

6. Electric field therapy is included in the National Comprehensive Care Network ("NCCN") guidelines for treatment with standard brain radiation therapy for central nervous system cancers for 2016. (Exh.1, pp. 87, 88). A letter from the Appellant's representative and attorney states the FDA deemed it unethical to withhold TTFT from those not receiving it during the clinical trial and ordered the sponsor to discontinue the study. This was the first time the FDA stopped a brain tumor study. (Exh. 3, p. 1).

LEGAL FRAMEWORK

A. Jurisdiction/Scope of Review/Standard of Review

OMHA has jurisdiction to hear appeals of QIC reconsiderations. 42 C.F.R. § 405.1002. ALJ decisions bind parties unless the Medicare Appeals Council ("Council") reviews or the case is escalated to Federal district court. 42 C.F.R. § 405.1048. ALJ decisions are reviewed by the Council in accordance with §§ 405.980, 405.1110, and 405.1138.

The issues before the ALJ include issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the appellant's favor. 42 C.F.R. § 405.1032(a). The ALJ conducts *de novo* review and issues a decision based on the record. 42 C.F.R. § 405.1000(d).

PRINCIPLES OF LAW

A. Statutes and Regulations

Section 1831 establishes the Supplemental Medical Insurance Program for the aged and disabled under Medicare Part B. Section 1832 establishes the scope of benefits that are provided to beneficiaries under the Medicare Part B insurance program. Under § 1832(a)(2)(B), an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with them made by a provider of services. (*See also* 42 CFR § 410.3). Section 1833(e) provides that "[n]o payment shall be made to any provider of services . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider . . . ." (*See also* 42 CFR § 424.5(a)(6)).

Section 1862(a)(1)(A) of Title XVIII of the Social Security Act (SSA) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1861(s)(6) defines the term "medical and other health services." (*See also* 42 CFR § 410.10(h)). Also considered is 42 CFR § 414.200-232 implementing §§ 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries. Section 1862(a)(1)(A) provides that notwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. (*See also* 42 CFR § 411.15(k)).

The Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicare program, has established a coding system for screening, processing, identifying, and paying Medicare claims—the Healthcare Common Procedure Coding System (HCPCS). The HCPCS incorporates codes developed by the American Medical Association, Current Procedure Terminology (CPT) codes, to identify and describe medical services and items. (*See* 42 C.P.R. §§ 414.2, 414.40).

B. National Coverage Determinations

A National Coverage Determination ("NCD"), if applicable, is binding on the ALJ. 42 C.F.R. §405.1060(a)(4).

C. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by Centers for Medicare and Medicaid Services ("CMS"), no rule, requirement, or statement of policy, other than an NCD, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. See also 42 C.F.R. §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that establishes criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs"). Administrative Law Judges are not bound by LCDs, but will give substantial deference to these policies when applicable. If an Administrative Law Judge does not follow a policy in a particular case, the Administrative Law Judge must explain why in the decision. 42 C.F.R. §405.1062.

When a NCD or LCD or other directives are lacking, the adjudication process requires the Judge to determine coverage by performing the same review that Medicare contractors, according to the Medicare Program Integrity Manual (Publ. 100-08), Chapter 13.7.1, would perform when developing a LCD.

> Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item/service in question. In order of preference, LCDs should be based on:
>
> - Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
> - General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
> - Scientific data or research studies published in peer-reviewed medical journals;
> - Consensus of expert medical opinion (i.e., recognized authorities in the field: or
> - Medical opinion derived from consultations with medical associations or other health care experts.

Local Coverage Determination L34823 entitled "Tumor Treatment Field Therapy" provides coverage guidance in this case: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. Policy Article A52711 provides further guidance by stating "in order

for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met."

ANALYSIS

The QIC determined the local coverage determination states tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. In this instance, the submitted documentation indicates the Beneficiary has a diagnosis of glioblastoma multiform involving the left occipital lobe. However, the medical documentation does not support the need for the device. There is insufficient documentation to quantify the effects of the device. The currently published studies in the medical literature do not clearly document the effectiveness of this device. As such, payment cannot be allowed. Based on available documentation, the requirements of the LCD have not been met. (Exh. 1, p. 4). The QIC determined an Advance Beneficiary Notice ("ABN") was not issued and the Provider was found liable. (Exh. 1, p. 5).

Local Coverage Determination L34823 entitled "Tumor Treatment Field Therapy" provides coverage guidance in this case: Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. National Government Services, Inc. Local Coverage Determination L34823: Tumor Treatment Field Therapy ("TTFT") (L34823) (October 2017). Policy Article A52711 provides further guidance by stating "in order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met." Also, administrative law judges are not bound by LCDs, but will give substantial deference to these policies when applicable. If an administrative law judge does not follow a policy in a particular case, the administrative law judge must explain why in the decision. 42 C.F.R. §405.1062.

Attorney Noonan states the Optune System is the subject of an LCD reconsideration request. In response to the request, the DME MAC medical directors sent a letter stating the LCD does not apply to cases with newly diagnosed glioblastoma. The Appellant is a newly diagnosed patient for the dates of service at issue. There is no district court decision on the coverage of the device and the medical directors do not believe the LCDs apply in the new cases. Also, the QIC denied because effectiveness could not be quantified. But, this is not a requirement for Medicare coverage. Even so, the Beneficiary has been alive for over 7 years since the diagnosis. Mr. McCoy, Case Manager for Novocure, Inc., testified and argued, in relevant part how no response has been received yet for the request made to contractors to reconsider the LCD to cover the service. He also testified the Appellant has been using the device for 7 years. (Hearing CD).

The Medicare coverage requirements are met. The Beneficiary was diagnosed with glioblastoma multiform in 2011. (Exh. 2, pp. 1, 25). The attending physician sought coverage for Optune for the Beneficiary with newly diagnosed glioblastoma and prescriptions cover the dates of service. (Exh. 2, pp. 1, 2, 4). Assessment of need and the agreement with Novocure indicate the treatment would be administered in the home under Part B rather than under an inpatient Part A admission. (Exh. 2, pp. 6, 8). Administrative law judges are not bound by LCDs, but must provide substantial deference. If an LCD is not followed, the ALJ must explain why in the decision. 42 C.F.R. §405.1062. In this case, the undersigned declines to follow the LCD while also providing substantial deference. As described above, local coverage determination ("LCD") L34823 finds the TTFT not medically reasonable and necessary. But, studies from the FDA and new literature from the medical community since the LCD was first issued show the treatment is beneficial to patients such as the Appellant and is medically reasonable and necessary. Examining the process

for how contractors make coverage determinations is helpful in establishing medical necessity for the service outside the determination. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item/service in question. In order of preference, LCDs should be based on general acceptance by the medical community (standard of practice), as supported by sound medical evidence based on scientific data or research studies published in peer-reviewed medical journals, consensus of expert medical opinion (i.e., recognized authorities in the field: or medical opinion derived from consultations with medical associations or other health care experts. MPIM ch. 13 § 7.1. General acceptance in the medical community is supported by sound medical evidence based on scientific data or research studies. Optune is approved by the FDA for recurrent glioblastoma multiforme. (Exh. 2, p. 94). The FDA discontinuing the initial study for those not receiving it suggests the treatment was medically necessary for the entire group based on scientific data. (Exh. 3, p. 1). Also, a general acceptance in the medical community is documented by electric field therapy inclusion in the NCCN guidelines for treatment with standard brain radiation therapy. (Exh.1, p. 88). Finally, sound medical evidence is further shown in the study published by the Journal of the American Medical Association ("JAMA") finding adding TTFields to maintenance chemotherapy significantly prolonged progress-free and overall survival. Medical opinion derived from consultations with a medical association is also shown by the study. (Exh. 1, p. 92). The Appellant has been using the treatment at issue for 7 years and Optune is subject to an LCD reconsideration request. Further, the DME MAC medical directors state the applicable LCD does not apply to newly formed glioblastoma like the Appellant's. (Hearing CD). The undersigned departs from the LCD because there is evidence showing acceptance and use in the medical community for the diagnosis at issue as documented by studies and articles in the record. The Appellant/Beneficiary was diagnosed with glioblastoma multiforme and the treatment received is supported by the included guidance. Taking the prior into consideration, the Medicare coverage requirements are met for the dates of service.

The service is medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. The Appellant is entitled to Medicare coverage for the Elec Stim Cancer Treatment (E0766) provided on the dates of service.

CONCLUSIONS OF LAW

Accordingly and after careful consideration, there is sufficient evidence supporting the Elec Stim Cancer Treatment (E0766) provided on the dates of service meets Medicare coverage criteria. The service was medically reasonable and necessary as required by Section 1862(a)(1)(A) of the Act and the Appellant is entitled to Medicare coverage.

ORDER

The Medicare Contractor is **DIRECTED** to process the appeal in accordance with this decision.

NOV - 7 2018

Dated: _____

SO ORDERED.

Jeffrey S. Gulin
U.S. Administrative Law Judge

2019058X01354

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF MEDICARE HEARINGS AND APPEALS

NOTICE OF NONDISCRIMINATION

The Office of Medicare Hearings and Appeals (OMHA) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. OMHA does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa (866) 207-4466.

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số (866) 207-4466.

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주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. (866) 207-4466 번으로 전화해 주십시오.

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: (866) 207-4466.

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ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele (866) 207-4466.

ध्यान दें: यदि आप हिंदी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। (866) 207-4466 पर कॉल करें।

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para (866) 207-4466.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

ATTACHMENT B:

Letter from the DMAC Medical Directors

CGS
A CELERIAN GROUP COMPANY

Two Vantage Way
Nashville, TN 37228
Telephone: 615-782-4476
Fax: 615-664-5955
robert.hoover@cgsadmin.com

August 7, 2018

Justin M. Kelly, RN, BSN
Novocure
195 Commerce Way
Portsmouth, NH 03801
Via email to: jkelly@novocure.com

Re: Tumor Treatment Fields Therapy (TTFT - LCD 34823) Reconsideration Request

Dear Mr. Kelly,

The DME MAC Medical Directors (DMDs) received your June 20, 2018 email to Dr. Robert Hoover requesting a formal reconsideration of the TTFT Local Coverage Determination (LCD) coverage criteria. Our response to your reconsideration request was originally due on July 20, 2018; however, it was delayed due to an inquiry to CMS.

Currently, the TTFT LCD includes language indicating that the coverage of TTFT for recurrent glioblastoma multiforme (GBM) is not reasonable and necessary. Coverage of newly diagnosed GBM is not addressed. Your letter asks that we revise the LCD to allow coverage for recurrent GBM and add coverage for newly diagnosed GBM. You provided draft language for both indications:

TTFT is covered as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma (GBM).

TTFT with temozolomide (TMZ) is covered for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, TTFT is covered following histologically- or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. TTFT is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

You provided the following articles from peer-reviewed sources in support of your request:

1. Stupp R, Taillibert S , Kanner A, et al. Effect of Tumor-Treating Fields Plus Maintenance Temozolomide vs Maintenance Temozolomide Alone on Survival in Patients With Glioblastoma A Randomized Clinical Trial. JAMA. 2017;318(23):2306-2316. doi:10.1001/jama.2017.18718
2. Taphoorn MJB, Dirven L, Kanner AA, Lavy-Shahaf G, Weinberg U, Taillibert S, Toms SA, Honnorat J, Chen TC, Sroubek J, David C, Idbaih A, Easaw JC, Kim CY, Bruna J, Hottinger AF, Kew Y, Roth P, Desai R, Villano JL, Kirson ED, Ram Z, Stupp R.

Influence of Treatment With Tumor-Treating Fields on Health-Related Quality of Life of Patients With Newly Diagnosed Glioblastoma: A Secondary Analysis of a Randomized Clinical Trial. JAMA Oncol. 2018 Apr 1;4(4):495-504. doi: 10.1001/jamaoncol.2017.5082.

3. Stupp R, Taillibert S, Kanner AA, et al. Maintenance therapy with tumor-treating fields plus temozolomide vs temozolomide alone for glioblastoma: a randomized clinical trial. JAMA. 2015;314(23):2535-2543.
4. Stupp R, Wong ET, Kanner AK, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: A randomised phase III trial of a novel treatment modality. Eur J Cancer. 2012;48;14:2192-2202.

Finally, in addition to the above-cited literature, you included excerpted information from the National Comprehensive Cancer Network (NCCN) guidelines v1.2018.

The DMDs will address each reconsideration request individually. The process for LCD reconsiderations is detailed in the Centers for Medicare & Medicaid Services (CMS) *Program Integrity Manual* (Internet-only manual 100-08), Chapter 13, §13.11. Based on this guidance, the DME MAC medical directors have determined that:

Newly diagnosed GBM: Valid request

Recurrent GBM: Invalid request
Rationale: As noted in the *Program Integrity Manual,* Ch. 13, §13.11:
Requests shall be submitted in writing, and shall identify the language that the requestor wants added to or deleted from an LCD. ***Requests shall include a justification supported by new evidence****, which may materially affect the LCD's content or basis. Copies of published evidence shall be included.* [Emphasis added]

The literature submitted in support of the coverage reconsideration for recurrent GBM was the Stupp article from the *European Journal of Cancer* (2012). This article was part of the bibliography considered with the initial development of the TTFT LCD. No additional clinical literature was submitted with the current reconsideration request.

With the acceptance of the valid request to add coverage for newly diagnosed GBM, according to the process defined in the Medicare Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, we must provide you with a final decision within 90 days following the receipt of a valid request. We received your completed request on June 20, 2018; therefore, we will notify you of our decision by September 18, 2018.

We appreciate your interest in our policy development process.

Sincerely,

Robert D. Hoover, Jr., MD, MPH, FACP

On behalf of:

Wilfred Mamuya, MD, PhD Medical Director, DME MAC, Jurisdiction A Noridian Healthcare Solutions 900 42nd Street South Fargo, ND 58103-2146 wilfred.mamuya@noridian.com	Robert D. Hoover, Jr., MD, MPH, FACP Medical Director, DME MAC, Jurisdiction C CGS Administrators, LLC 2 Vantage Way Nashville, TN 37228-1504 robert.hoover@cgsadmin.com
Stacey V. Brennan, MD, FAAFP Medical Director, DME MAC, Jurisdiction B CGS Administrators, LLC 2 Vantage Way Nashville, TN 37228-1504 stacey.brennan@cgsadmin.com	Peter J. Gurk, MD, CPE, CHCQM Medical Director, DME MAC, Jurisdiction D Noridian Healthcare Solutions 900 42nd Street South Fargo, ND 58103-2146 peter.gurk@noridian.com